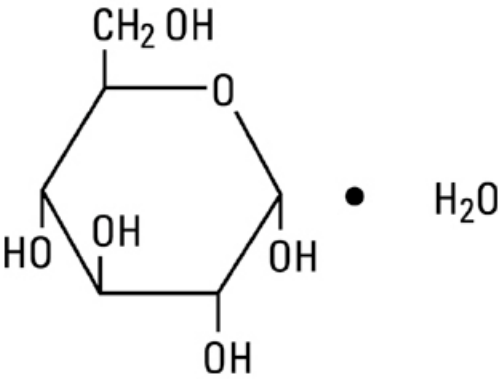
IONOSOL AND DEXTROSE - dextrose hydrous, sodium chloride, potassium chloride, potassium lactate and sodium phosphate, monobasic, monohydrate injection, solution
Hospira

A REPLACEMENT OR MAINTENANCE ELECTROLYTE SOLUTION
Flexible Plastic Container
R_x only

DESCRIPTION

Ionosol T and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Injection Type 3, USP) is a sterile, nonpyrogenic fluid electrolyte replenisher and nutrient for intravenous administration.
Each 100 mL contains dextrose, hydrous 5 g; sodium chloride 146 mg; potassium chloride 111 mg; potassium lactate, anhydrous 256 mg; monobasic sodium phosphate, monohydrate 207 mg. The pH is 5.0 (4.0 to 6.5); the osmolarity (calc.) is 432 mOsmol/L. Each liter contains sodium, 40 mEq; potassium, 35 mEq; chloride, 40 mEq; phosphate ($PO_4^{\equiv}$), 15 mM; and lactate, 20 mEq.
Dextrose, USP, hydrous is chemically designated $C_6H_{12}O_6 \cdot H_2O$ (D-glucose, monohydrate), a hexose sugar freely soluble in water.
Dextrose, hydrous has the following structural formula:



Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.
Potassium lactate, anhydrous is chemically designated $CH_3CH(OH)COOK$, a thick liquid miscible in water.
Sodium Chloride, USP is chemically designated NaCl, a white crystalline compound freely soluble in water.
Monobasic Sodium Phosphate, USP, monohydrate is chemically designated $NaH_2PO_4 \cdot H_2O$, white crystals or granules freely soluble in water.
Water for Injection, USP is chemically designated H_2O.
The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions inside the plastic container also can leach out certain of their chemical components in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.

CLINICAL PHARMACOLOGY

When administered intravenously, Ionosol T and 5% Dextrose Injection provides a source of water, electrolytes, and carbohydrate. The solution was originally designed as a pediatric fluid/electrolyte replacement formula, providing nearly equal amounts of sodium, potassium, and chloride; phosphate and lactate are also present, along with dextrose.
Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.
The lactate anion provides an alkalizing effect resulting from simultaneous removal by the liver of lactate and hydrogen ions. In the liver, the lactate is metabolized to glycogen which is ultimately converted to carbon dioxide and water by oxidative metabolism. The lactate anion acts as a source (alternate) of bicarbonate when normal production and utilization of lactic acid is not impaired as a result of disordered lactate metabolism. Since metabolic conversion is dependent on the integrity of cellular oxidative processes, lactate may be inadequate or ineffective as a source of bicarbonate in patients suffering from acidosis associated with shock or other disorders involving reduced perfusion of body tissues. When oxidative activity is intact, one to two hours time is required for metabolism of lactate.
Phosphate is one of the three major intracellular electrolytes (along with potassium and magnesium) and the largest anion component found within the cells. Its concentration and excretion are largely dependent on intake, acid-base balance and endocrine function. Its metabolism follows that of calcium in many respects. Phosphate anion in electrolyte solutions may help to repair phosphate deficiency.

Potassium chloride in water dissociates to provide potassium (K^+) and chloride (Cl^-) ions. Potassium is the chief cation of body cells (160 mEq/liter of intracellular water). It is found in low concentration in plasma and extracellular fluids (3.5 to 5.0 mEq/liter in a healthy adult). Potassium plays an important role in electrolyte balance. Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.
Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production). Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments, and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.
Ionosol T and 5% Dextrose Injection contains a hypotonic electrolyte concentration. This should not be confused with the total tonicity (electrolytes plus nonelectrolytes) of solutions containing both electrolytes and dextrose. In general, solutions providing isotonic electrolyte concentrations are most applicable to replacement of acute deficits, whereas hypotonic electrolyte concentrations are best suited for parenteral maintenance of water requirements when only small quantities of electrolytes are desired.

INDICATIONS AND USAGE
Ionosol T and 5% Dextrose Injection is used to provide water, carbohydrate, and electrolytes to cover hydration, insensible water losses and urinary excretion. The electrolyte content of the solution is hypotonic, but the tonicity of the total solution is hypertonic.

CONTRAINDICATIONS
Solutions containing potassium are contraindicated in diseases where high potassium levels may be encountered.

WARNINGS
Solutions which contain potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.
Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.
Inpatients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.
Solutions containing lactate ions should be used with great care, if at all, in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of lactate ions, such as severe hepatic insufficiency.
The intravenous administration of Ionosol T and 5% Dextrose Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.
The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

PRECAUTIONS
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.
Solutions containing lactate ions should be used with caution as excess administration may result in metabolic alkalosis.
Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.
Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Pregnancy Category C.
Animal reproduction studies have not been conducted with Ionosol solutions. It is also not known whether Ionosol solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ionosol solutions should be given to a pregnant woman only if clearly needed.

Geriatric Use:
An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE
In the event of overhydration or solute overload during therapy, re-evaluate the patient and institute appropriate corrective measures. See WARNINGS and PRECAUTIONS.

DOSAGE AND ADMINISTRATION
The dose is dependent upon the age, weight and clinical condition of the patient.
Drug Interactions
Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. See PRECAUTIONS.
INSTRUCTIONS FOR USE
To Open:
Tear outer wrap at notch and remove solution container. Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.
If supplemental medication is desired, follow directions below before preparing for administration.
To Add Medication
1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

Preparation for Administration
(Use Aseptic Technique)
1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated. **NOTE:** When using a vented administration set, replace bacterial retentive air filter with piercing pin cover. Insert piercing pin with twisting motion until shoulder of air filter housing rests against the outlet port flange. **NOTE:** See full directions on administration set carton.
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open flow control clamp and clear air from set. Close flow control clamp.
7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
8. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

Ionosol T and 5% Dextrose Injection (Multiple Electrolytes and 5% Dextrose Injection Type 3, USP) is supplied in flexible plastic containers providing 500 and 1000 mL fluid volumes (List No. 7373).

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

 EN-0507 Printed in USA

HOSPIRA, INC., LAKE FOREST, IL 60045 USA